Attorney's Docket No.: 00633-030002 / 00/037D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Dimitri Azar	Art Unit	: 3738
Serial No.	: 10/627,943	Examiner	: William H. Matthews
Filed	: July 25, 2003		
Title	: VISION PROSTHESIS		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

(1) Real Party in Interest

The real party in interest is the Massachusetts Eye and Ear Infirmary, a Massachusetts corporation having a place of business at 243 Charles Street, Boston, Massachusetts, as evidenced by an assignment executed June 21, 2001 and submitted for recordation at the U.S. Patent Office on August 7, 2001. The assignment was recorded at reel 012070 frame 0715 on August 10, 2001.

(2) Related Appeals and Interferences

Neither Applicant, nor Applicant's legal representative, nor the assignee are aware of any appeals or interferences that will directly affect or be affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

Independent claims 1, 22, and 48 are pending.

The pending claims that ultimately depend on claim 1 are claims 3-8, 10-11, 14-16, 27-29, and 31.

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The pending claims that ultimately depend on claim 22 are claims 23 and 24.

The pending claims that ultimately depend on claim 48 are claim 49, and claims 53-58.

Claims 9, 12-13, 17-21, 25-26, and 32-47 have been cancelled.

Claims 50-52 have been withdrawn as being directed to a non-elected invention.

(4) Status of Amendments

Applicant last amended the claims in a response to the non-final office action of December 20, 2004. These amendments have been entered.

(5) Summary of Claimed Subject Matter

Applicant has recognized that the brain attempts to focus the lens even when the lens is absent (as in aphakic patients) or insufficiently flexible. In doing so, the brain causes various intraocular structures to undergo changes associated with focusing the lens. These changes provide cues that can be used to focus an artificial lens. For example, in attempting to focus the lens, the brain causes contraction of the ciliary muscle, which in turn causes tensioning of the zonules. The brain also stimulates the iris muscle to contract the pupil, and stimulates the rectus muscle to cause the eyes to converge.

Applicant's invention is essentially to intercept one or more of these cues and to use the information provided therein to focus an artificial lens. Essentially, Applicant's invention hijacks the brain's attempts to focus the natural lens and uses those attempts to focus an artificial lens instead.

The claimed rangefinder is the device that intercepts a cue, extracts from that cue information about the brain's attempt to focus, and provides that information to the controller, which then causes the intraocular lens to respond appropriately. Embodiments of the rangefinder include those that sense contraction in the ciliary muscle, contraction of the pupil, tension in the zonule, and contraction of the rectus muscle, as well as electrical activity associated with the brain's attempts to focus the lens.

Independent claim 1 recites elements of an apparatus for automatically varying the focus of a lens implanted into the eye. The claimed apparatus features an intraocular lens having a variable index of refraction and an actuator that causes the index to change in response to a focusing stimulus provided by a controller. The controller generates the focusing stimulus on the basis of a range estimate provided by a rangefinder. The rangefinder generates a range estimate indicative of a relative distance to an object of regard.

Independent claim 22 is identical to claim 1 with two exceptions: the lens no longer needs to be an intraocular lens, and the rangefinder now includes a transducer for detecting a stimulus from an anatomic structure of the eye.

Independent claim 48 is identical to claim 1 except that the intraocular lens with its variable index of refraction is replaced by an intraocular lens system with a variable focal length.

The claims dependent on claim 1 are summarized as follows:

Dependent claims 3-8 all add structural limitations on the nature of the lens. Claims 3-5 add limitations that affect where the lens is implanted. Claim 6, which recites a foldable lens, affects how the lens is implanted. Dependent claims 7-8 add limitations on a particular way that the lens achieves its variable index of refraction, which in this case is through use of nematic liquid crystal.

Dependent claims 10-11, and 14-16 add limitations related to the actuator. Claim 10 recites actuators that include a variable voltage source. Claim 11 adds to this an electrode that couples the voltage source to the lens. Claims 14-16 are directed to embodiments in which different parts of the lens can have different indices of refraction.

Claims 27-29 add limitations related to rangefinders. In particular, claim 27 recites an auto focus system. Claims 28 recites an auto focus system that determines range on the basis of a reflected infrared beam. Claim 29 recites an auto focus system having a feedback loop.

Claim 31 is directed to an embodiment in which there exists a way to manually override the signal provided by the controller.

The claims dependent on claim 26 all recite variations on the transducer. Claim 23 is directed to embodiments in which the transducer is a pressure transducer that detects contraction of muscle. Claim 24 adds the further limitation that the pressure transducer includes a piezoelectric element.

The claims dependent on claim 48 are summarized as follows:

Claim 49 is directed to embodiments in which the index of refraction varies in response to the focusing stimulus.

Claims 53 and 57-58 are directed to variants of the rangefinder. Claim 53 recites rangefinders that include a transducer for receiving a signal indicative of distance to an object. Claims 57-58 are directed to rangefinders that use activity of an intraocular structure to determine range.

(6) Grounds of Rejection

Independent claim 1 and all its progeny, except claims 27-29, stand rejected as being anticipated by *Grendahl.*[1]

Independent claim 48, and all its progeny except claims 53 and claims 57-58, stand rejected as being anticipated by *Grendahl.*

Independent claim 22 and its progeny stand rejected as being anticipated by *Grendahl.*

In addition, both independent claims 22 and 48, and dependent claim 53, stand rejected as being anticipated by *Piosenka.*[2]

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[1] *Grendahl,* U.S. Patent No. 4,787,903.
[2] *Piosenka et al.*, U.S. Patent No. 5,359,444.

Claims 27 and 28, which depend ultimately on independent claim 1, and claims 57-58, which depend ultimately on independent claim 48, stand rejected as being rendered obvious by the combination of *Grendahl* and *Piosenka*.

Finally, dependent claims 57-58, which depend ultimately on claim 48, stand rejected as being rendered obvious by *Grendahl*, *Piosenka*, and *Freger*.[3]

(7) Argument

Section 102 rejection of claims 1, 3, 4, 5, 10, 7, 11, 14, 15, 31, 48, 49, 54, 55 based on *Grendahl*

The foregoing claims all stand rejected as being anticipated by *Grendahl*. These claims all recite the limitation of a rangefinder and a controller.

As best understood, the Examiner considers the claimed lens to correspond to *Grendahl*'s lens optic **12** in combination with the overlay **22** and the variable index material **24** embedded therein. The claimed actuator would then be either the piezoelectric material **104, 106** or the coil **28**. The index of refraction is apparently changed by either applying a force to the piezoelectric material, as discussed in connection with FIGS. 9 and 10, or by application of a field, as discussed in connection with FIG. 9.

Grendahl discloses that the user applies the force by pressing on his eyeball.[4] *Grendahl* does not describe what controls the current in the coil 28.

The Examiner evidently concedes that *Grendahl* fails to disclose the claimed rangefinder and controller. However, the Examiner's position is that a rangefinder and controller are inherently disclosed by *Grendahl*.

The Examiner has evidently cast the user of the *Grendahl* device as playing the roles of both the controller and the rangefinder. In particular, when the user makes a subjective judgment

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[3] *Freger*, U.S. Patent No. 5,793,704.

[4] *Grendahl*, col. 3, lines 10-14 (The piezoelectric material generates energy when pressure is applied against the loops such as by one pressing on the eyeball...).

as to whether an image is in focus, he functions as the claimed rangefinder. When he then presses on his eyeball in response to that judgment, he acts as the claimed controller.

Applicant draws attention to the distinction between a human being carrying out a claimed step in a method claim and casting a human being as a claimed element in an apparatus claim.

It is well established that a claimed step of a method claim can be anticipated by a human being who performs that step. The same is not true for apparatus claims. It is improper to cast a human being in the role of an element in an apparatus claim.

In support of the proposition that one may not cast a human as a claim element, Applicant draws attention to *Default Proof*, in which the patentee, faced with an absence of any disclosed structure in the specification for a "means for dispensing" a debit card, attempted to persuade the District Court that a human being who participated in the function for dispensing a debit card was the corresponding structure.[5]The District Court "declined to rule that the structure corresponding to the 'means for dispensing' may include acts by a human being, i.e., a person manually operating the dispensing apparatus."[6] The District Court further pointed out that "the case law precludes a conclusion that a human being is a corresponding structure, or an equivalent to a structures under 35 USC 112 paragraph 6."[7]

In affirming the District Court, the Federal Circuit stated:

> Default Proof's arguments that the structure corresponding to the "means for dispensing" can entail human (or "merchant") participation or a human being manually operating an apparatus, are equally misplaced. Given that a human being cannot constitute a "means," see *In re Prater*, 415 F.2d 1393, 1398 (CCPA 1969), Default Proof's arguments merely beg the question of what structure the human being operates to perform the function of distributing the prepaid debit cards.

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[5] *Default Proof Credit Card Systems v. Home Depot U.S.A.*, 412 F.3d 1291, 1300 (Fed. Cir. 2005).
[6] *Default Proof*, at 1297.
[7] *Id.*

Applicant recognizes that the present claims are not in means-plus-function format. However, Applicant submits that nothing in *Default Proof* suggests that the essentially functional recitations of the claimed rangefinder and controller should be treated any differently.

In the alternative, Applicant submits that construing the rangefinder to be a human being goes well beyond the broadest reasonable interpretation of the term "rangefinder."

Human beings are notoriously poor at judging distance. It is to overcome this deficiency that methods such as triangulation, or time-domain reflectometry, have been invented. It is unclear why one of ordinary skill in the art would interpret "rangefinder" to include a "device" (i.e. a human being) that is notoriously unreliable at judging distance.

It is understood that the foregoing arguments apply to all claims dependent on claims 1, 22, and 48.

Section 102 rejection of claim 6 based on *Grendahl*

Claim 6 recites the additional limitation of a foldable lens having a tendency to spring back into an unfolded state. In neither the first office action nor the second office action has the Examiner drawn attention to any language in *Grendahl* that discloses a foldable lens. Applicant has been unable to find any such disclosure. Accordingly, Applicant submits that *Grendahl* fails to anticipate claim 6.

Section 102 rejection of claim 8 based on *Grendahl*

Claim 8 recites the limitation that the chamber containing nematic liquid crystal be thinner than the gap between the eye's lens bag and iris.

As best understood, the Examiner considers the chamber recited in claims 7 and 8 to be whatever contains the variable index material **24** in FIG. 3. Presumably, the planar surfaces recited in the claim would be the surface of the overlay **22**, which in FIG. 3 would be the free surface facing the loop **28** and the lens-facing surface.

As a threshold matter, the lens-facing surface of the overlay 22 is not even a planar surface, as required by the claim. It is shaped to conform to the non-planar surface of the Fresnel

lens. In addition, *Grendahl* is silent on any constraints on the distance between these two surfaces of the overlay **22**. Accordingly, Applicant submits that *Grendahl* fails to anticipate claim 8.

Section 102 rejection of claim 56 based on *Grendahl*

Claim 56, which stands rejected as being anticipated by *Grendahl*, recites the limitation of a force transducer that receives a signal indicative of a distance to an object of regard. This force transducer is in mechanical communication with a zonule, a ciliary muscle, a media rectus muscle, a lens bag, and an iris.

The Examiner has not drawn attention to any disclosure in *Grendahl* of a force transducer in mechanical communication with any one of these structures. Applicant speculates that the Examiner may be referring to *Grendahl*'s disclosure of an embodiment in which a piezoelectric material **108, 110** in the loops responds to pressure placed on the device by the wearer. However, the piezoelectric material **108, 110** does not appear to be in communication with any of the foregoing structures.

In Applicant's invention, mechanical activity in any of the listed structures is intended, ultimately, to cause the actuator to provide the focusing stimulus. In *Grendahl*, the focusing stimulus appears to originate from the force applied by the user's hand as he presses against his eye.

Applicant submits that *Grendahl* fails to teach or suggest a force transducer that is in mechanical communication with any of the foregoing structures.

Section 102 rejection of claim 22 based on *Grendahl*

Claim 22 recites the additional limitation that the rangefinder have a transducer for detecting a stimulus from an anatomic structure in an eye.

The Examiner has not identified any such transducer. The only transducer disclosed in *Grendahl* is the piezoelectric material. However, as disclosed by *Grendahl*, the user presses on the eyeball to stimulate the piezoelectric material. Hence, it does not appear that the piezoelectric material detects a stimulus from an anatomic structure in an eye.

Accordingly, Applicant submits that the section 102 rejection of claim 22 is improper insofar as it relies on *Grendahl.*

Section 102 rejection of claim 22 based on *Piosenka*

Independent claim 22 stands rejected as being anticipated by *Piosenka*.

The only structure in *Piosenka* that can be said to detect "a stimulus from an anatomic structure in an eye" is the secondary cornea tracking system **76**. However, according to *Piosenka*, the "secondary cornea tracking system 76 is used to measure the orientation of the eye by an infrared signal reflected from the cornea."[8] The resulting signal "provides information about the temporal location of the line of vision."[9] As best understood from this text, the cornea tracker **76** tells the computer system **71** which way the user is looking.

Applicant notes the disclosure in *Piosenka* of an IR ranging system **75**. However, this system does not appear to "include a transducer for detecting a stimulus from an anatomic structure in an eye." *Piosenka* describes a range finding system that measures how long it takes for an IR pulse to reflect from a target.[10] This has nothing to do with detecting a stimulus from anything in the eye.

Section 102 rejection of claim 48 based on *Piosenka*

Independent claim 48 stands rejected as being anticipated by *Piosenka*.

Applicant reiterates the argument set forth in connection with independent claim 22 concerning the distinction between the claimed rangefinder and the corneal tracking device of *Piosenka* and the absence therein of a rangefinder that includes a transducer that detects a stimulus from an anatomic structure in the eye.

However, claim 48 also recites the additional limitation of an *intraocular* lens system. *Piosenka* discloses a lens system mounted on a pair of eyeglasses.

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[8] *Piosenka*, col. 6, lines 4-6.
[9] *Piosenka*, col. 6, lines 8-9.
[10] *Piosenka*, col. 5, lines 55-66.

Accordingly, the section 102 rejection of claim 48 is improper both because of the reasons discussed in connection with claim 22 and because *Piosenka* fails to disclose an *intraocular* lens system.

Section 103 rejection of claims 27, 28, and 58

Claim 27 recites the additional limitation that the rangefinder include an autofocus system. Claim 28 requires that the autofocus system include an IR transmitter and receiver, and a processor that estimates a range based on the received IR signal.

The Examiner concedes that *Grendahl* fails to disclose such a system, but then proposes combining the IR autofocus system of *Piosenka* with the intraocular lens of *Grendahl*. As a motivation for this combination, the Examiner suggests that this would enable the *Grendahl* system to properly determine distance to objects.

Applicant reasserts the arguments set forth above in connection with claim 1, from which claims 27 and 28 depend.

In addition, Applicant submits that the proposed motivation to combine the references makes no sense. According to the Examiner, *Grendahl* inherently has a rangefinder, namely the human being that presses his eyeball to actuate the piezoelectric elements. The Examiner appears to propose replacing the human being with the IR system of *Piosenka*.

The *Grendahl* intraocular lens is focused with no knowledge of the actual distance to an object of regard. Therefore, there is no need to obtain that distance from the IR autofocus system of *Piosenka*. The *Grendahl* device is only intended to focus an image. It achieves this focus by relying on the user, who perceives an unfocused image, and then presses against his eyeball to change the focus of the image.

It is difficult to imagine how knowing the exact distance to an object would have any connection with the operation of the *Grendahl* lens. After all, the wearer of the *Grendahl* lens does not focus it by measuring the distance to an object, reading the distance, and then pressing

his eyeball with a force commensurate with the measured distance. Instead, he simply looks at the image, decides if it is out-of-focus, and presses his eyeball as required to bring it into focus.

The proposed modification, which includes replacing the human being as rangefinder with the IR system of *Piosenka*, would complicate this simple operation. After all, the human being as controller remains. Therefore there has to be a coupling between the new IR rangefinder and the human being as controller. It is unclear how such coupling is to take place. The only mechanism that comes to mind is that the human being would read a display showing a distance to an object, as provided by the *Piosenka* IR device, look up the correct amount of force to be applied to his eyeball, and then press his eyeball with the requisite force. Such a procedure is clearly far too cumbersome to be practical.

Section 103 rejection of claim 57

Claim 57 recites the additional limitation of a rangefinder that is configured to detect electrical activity associated with an intraocular structure.

The Examiner rejects claim 57 as being anticipated by the combination of *Grendahl* and *Piosenka*. However, the Examiner never addresses this limitation in the final office action. Paragraph 5 of the final office action only refers to combining the autofocus system of *Piosenka* with the lens of *Grendahl*.

Applicant has reviewed both *Grendahl* and *Piosenka* in an attempt to identify a component that detects electrical activity associated with an intraocular structure. However, there appears to be no such structure. Accordingly, the proposed combination would still fail to meet the limitation of claim 57. Accordingly, Applicant requests reversal of the section 103 rejection of claim 57.

Section 103 rejection of claim 29

Claim 29 adds to claim 27 the additional limitation of a feedback loop coupled to the auto-focus system. Such a feedback loop is used for rangefinders that are not connected to any intraocular structure. One such rangefinder is discussed in Applicant's specification on page 12, lines 1-21 in connection with FIG. 8.

The Examiner proposes to combine the feedback loop in FIG. 6 of *Freger* with the combination of *Grendahl* and *Piosenka*.

As motivation for this combination, the Examiner states that doing so would result in a device that can "more efficiently determine distance to objects."[11]However, this motivation makes little sense because the *Grendahl* intraocular lens is focused without regard to the actual measured distance to the object.

Additionally, the proposed combination makes little technical sense.

In FIG. 6, *Freger* discloses an ultrasound system in which the gain of an amplifier **84** is adjusted to prevent saturation of a receiver circuit **80**. The gain is adjusted by feedback that ultimately derives from the output of the amplifier **84**.

In *Freger*, the receiver receives a waveform having an envelope. This envelope has a maximum value. The time at which this maximum value arrives is critical to determining the range to the target. It is therefore important to avoid distortion by the receiver. As a result, it is desirable to avoid saturation, which can cause distortion.

According to *Freger*, the reason the maximum value of the amplitude envelope is so important is that the a measurement that relies on this maximum is relatively immune to variation in the speed of sound due to variations in humidity, temperature and pressure.[12]

This difficulty does not arise in the context of an infrared system like *Piosenka*'s because infrared light remains constant as it propagates through the atmosphere. Hence, it makes no sense to incorporate into the *Piosenka* IR ranging system 75 the feedback loop from *Freger* since to do so would be to include a solution for a problem that does not exist in *Piosenka*.

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[11] *Final Office Action*, page 5.

[12] *Freger*, col. 2, lines 26-29 ("Therefore, a range measurement based on picking the maximum of the amplitude envelope of the received echo pulse is relatively immune to variations in sound speed").

In addition to the foregoing arguments, which are directed to the combination of *Freger*, Applicant submits that the motivation to combine *Grendahl* and *Piosenka* makes no sense for reasons discussed in connection with claim 27.

The brief fee of $250 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: August 22 2005

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Appendix of Claims

1. **(Amended)** An apparatus comprising:

a lens adapted for implantation in an eye of a human patient, the lens having an index of refraction that varies in response to a focusing stimulus;

an actuator in communication with said lens for providing said focusing stimulus;

a rangefinder for generating a range estimate indicative of a relative distance to an object-of-regard; and

a controller coupled to said rangefinder and to said actuator for causing said actuator to generate a focusing stimulus on the basis of said range estimate.

2. **(Cancelled)**

3. **(Amended)** The apparatus of claim 1, wherein said lens is adapted for implantation at a location in an eye, said location being selected from the group consisting of:

the anterior chamber;

the posterior chamber;

the lens bag; and

the cornea.

4. **(Amended)** The apparatus of claim 1, wherein said lens is adapted for implantation in an aphakic human patient.

5. **(Amended)** The apparatus of claim 1, wherein said lens is adapted for implantation in a phakic human patient.

6. **(Original)** The apparatus of claim 1, wherein said lens is a foldable lens having a tendency to spring back into an unfolded state.

7. **(Original)** The apparatus of claim **1**, wherein said lens comprises a chamber containing nematic liquid crystal.

8. **(Original)** The apparatus of claim **7**, wherein said chamber comprises a first planar side and a second planar side opposed to said first planar side, said first and second planar sides being separated by a gap smaller than a separation between a lens bag in an eye and an iris in said eye.

9. **(Cancelled)**

10. **(Original)** The apparatus of claim **1**, wherein said actuator comprises a variable voltage source.

11. **(Original)** The apparatus of claim **10**, wherein said actuator further comprises an electrode coupled to said variable voltage source and to said lens for applying an electric field within said lens.

12.-13. **(Cancelled)**

14. **(Original)** The apparatus of claim **1**, wherein said actuator comprises a plurality of actuating elements coupled to different local regions of said lens for selectively varying said index of refraction at said different local regions of said lens.

15. **(Original)** The apparatus of claim **14**, wherein each of said local regions of said lens has a local curvature.

16. **(Original)** The apparatus of claim **14**, wherein said actuating elements comprise a plurality of electrodes disposed at different portions of said lens.

17-21. **(Cancelled)**

22. **(Amended)** An apparatus comprising:

a lens having an index of refraction that varies in response to a focusing stimulus;

an actuator in communication with said lens for providing said focusing stimulus;

a rangefinder for generating a range estimate indicative of a relative distance to an object-of-regard, said rangefinder including a transducer for detecting a stimulus from an anatomic structure in an eye, said stimulus being indicative of a range to said object-of-regard; and

a controller coupled to said rangefinder and to said actuator for causing said actuator to generate a focusing stimulus on the basis of said range estimate.

23. **(Amended)** The apparatus of claim **22**, wherein said transducer comprises a pressure transducer for detecting contraction of a muscle.

24. **(Amended)** The apparatus of claim **23**, wherein said pressure transducer comprises a piezoelectric element that generates a voltage in response to contraction of said muscle.

25-26. (Cancelled)

27. **(Original)** The apparatus of claim **1**, wherein said rangefinder comprises an autofocus system.

28. **(Original)** The apparatus of claim **27**, wherein said autofocus system comprises:

an infrared transmitter for illuminating an object with an infrared beam;

an infrared receiver for receiving a reflected beam from said object, and

a processor coupled to said infrared receiver for estimating a range to said object on the basis of said reflected beam.

29. **(Original)** The apparatus of claim **27**, wherein said rangefinder further comprises a feedback loop coupled to said autofocus system.

30. **(Cancelled)**

31. **(Original)** The apparatus of claim **1**, further comprising a manual focusing control for enabling a patient to fine tune focusing of said lens.

32-47. **(Cancelled)**

48. **(New)** An apparatus comprising:

an intraocular lens system having a focal length that varies in response to a focusing stimulus;

an actuator in communication with the lens system for providing the focusing stimulus;

a rangefinder for generating a range estimate indicative of a relative distance to an object-of-regard; and

a controller coupled to the rangefinder and to the actuator for causing the actuator to generate a focusing stimulus on the basis of the range estimate.

49. **(New)** The apparatus of claim **48**, wherein the lens system comprises an optically transmissive medium having an optical index that varies in response to the focusing stimulus.

50. **(New)** The apparatus of claim **48**, wherein the lens system comprises at least two lens elements that move relative to each other in response to the focusing stimulus.

51. **(New)** The apparatus of claim **48**, wherein the lens system comprises a lens element that moves in response to the focusing stimulus.

52. **(New)** The apparatus of claim **48**, wherein the lens system comprises an optically transmissive medium having a surface, at least a portion of which changes shape in response to the focusing stimulus.

53. **(New)** The apparatus of claim **48**, wherein the rangefinder comprises a transducer for receiving a signal indicative of the distance to the object-of-regard.

54. **(New)** The apparatus of claim **53**, wherein the transducer comprises a force transducer.

55. **(New)** The apparatus of claim **54**, wherein the force transducer is configured to be in mechanical communication with an intraocular structure.

56. **(New)** The apparatus of claim **55**, wherein the force transducer is configured to be in mechanical communication with an intraocular structure selected from the group consisting of a zonule, a ciliary muscle, a media rectus muscle, a lens bag, and an iris.

57. **(New)** The apparatus of claim **55**, wherein the rangefinder is configured to detect electrical activity associated with actuation of an intraocular structure.

58. **(New)** The apparatus of claim **55**, wherein the rangefinder comprises an auto focus system.